REMARKS/ARGUMENTS

Claims 15-17 and 21-36 are under examination in the application. The Office Action mailed on September 16, 2008, includes the following objections and rejections:

1. Claims 17 and 21-29 is rejected under 35 U.S.C. 112, second paragraph.

2. Claims 15-17 and 21-29 are rejected under 35 U.S.C. 112, first paragraph.

3. Claims 15-17 and 21-36 are rejected under 35 U.S.C. 103(a).

Claims 17 and 21-29 is rejected under 35 U.S.C. 112, second paragraph

Claims 17 and 21-29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants assert that the claims as amended fully comply with 35 U.S.C. § 112 and respectfully request the withdrawal of the rejection.

Claims 15-17 and 21-29 are rejected under 35 U.S.C. 112, first paragraph

Claims 15-17 and 21-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Applicants submit that the specification fully complies with the written description sufficiently to convey a skilled artisan that the Applicants were in possession of seven carbon fatty acid and derivatives thereof.

Specifically, the present invention provides a method of suppressing the effects of translocase deficiency of a prematurely-born human infant by identifying an infant suspected of having a translocase deficiency and administering to an infant suspected of having a translocase deficiency a composition comprising a seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives thereof. The specification as filed provides numerous examples of

the seven carbon fatty acid and derivatives thereof. In addition, the specification provides the structure and function of the claimed invention and numerous seven carbon fatty acid derivatives in paragraph [0076].

> [0076] Unsaturated heptanoates can also be utilized as a nutritional supplement to overcome fatty acid metabolism deficiencies. In addition, substituted, unsaturated, and/or branched seven-carbon fatty acids which readily enter the mitochondrion without special transport enzymes can be utilized in the present invention. For example, 4-methylhexanoate, 4-methylhexenoate, and 3-hydroxy-4-methylhexanoate are broken down by normal [beta]-oxidation to 2-methylbutyric acid with final degradation accomplished via the isoleucine pathway. Likewise, 5-methylhexanoate, 5-methylhexenoate, and 3-hydroxy-5-methylhexanoate are broken down by normal [beta]-oxidation to isovaleric acid with final degradation accomplished via the leucine pathway.

The specification provides the structure (e.g., seven carbon fatty acid) and provides some examples of the modification that can be used with the present invention (e.g., substituted (and un-substituted), unsaturated (and saturated), branched (and straight). In addition, the instant specification provides specific examples of different compositions to illustrate some of the modifications. As such, the instant specification provides a description of sufficient, relevant, identifying characteristics including structure and function, including numerous structure and various examples of specific compounds to convey a skilled artisan that the Applicants were in possession of seven carbon fatty acid and derivatives thereof of the instant invention.

An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. See, e.g., *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (the written description "inquiry is a factual one and must be assessed on a case-by-case basis"). Applicants assert that the specification fully complies with the written description sufficiently to convey a skilled artisan that the Applicants were in possession of the present invention. Specifically, the specification provides the structure of the composition, a fatty acid and specifically lists the

number of carbons in the fatty acid. As such, the skilled artisan would recognize that the skilled artisan is in possession of seven carbon fatty acid and derivatives thereof.

The instant specification discloses the structure in addition to other physical characteristics of the claimed invention and clearly discloses the function of the claimed invention. In addition, the instant specification disclose modifications of the structure and provides detailed examples of some of the various modifications of the seven carbon fatty acid. It is not necessary for the Applicants to disclose each and ever modification to the structure to comply with the written description requirement, only to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Applicants assert that the subject matter of the claims is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner is reminded that not everything necessary to practice the invention need be disclosed, in fact, what is well known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). See Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d at 1384, 231 USPQ at 94. See also Capon v. Eshhar, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005)("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge... As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution."). If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., Vas-Cath, 935 F.2d at 1563, 19 USPQ2d at 1116; Martin v. Johnson, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in ipsis verbis [i.e., "in the same words"] to be sufficient"). In fact, examples are not necessary to fulfill the requirements of 35 U.S.C. § 112, first paragraph. In fact, possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas, which permit a person skilled in the art to clearly recognize that applicant had

possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. See, e.g., Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (the written description "inquiry is a factual one and must be assessed on a case-by-case basis"). As such, the instant specification fully complies with the written description requirement by disclosing among other things the structure and numerous modifications to that structure.

The Applicants assert that the claims fully comply with the written description requirement of 35 U.S.C. § 112, first paragraph and the claims are described in the specification sufficiently to convey a skilled artisan that the inventors were in possession of the present invention. Accordingly, Applicants respectfully request withdrawn all 35 U.S.C. § 112 rejections.

Claims 15-17 and 21-36 are rejected under 35 U.S.C. 103(a)

Claims 15-17 and 21-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Odie, et al. (Journal of Nutrition, 1991, Vol. 121, pages 605-614; provided by Applicant, hereafter referred to as "Odie"), in view of Ajinomoto (JP 52015834A (provided by Applicant) hereafter referred to as "Ajinomoto") and Jandacek (US Patent No. 4,753,963 hereafter referred to as "Jandacek"). Applicant is fully aware of the above listed art as it was cited by the Applicants, and respectfully submit that the instant invention and the combination of cited art are different and the instant inventions is not rendered obvious by the cited combination. The combination fails on all counts to establish obviousness.

To establish a *prima facie* case of obviousness there must be: (1) some suggestion or motivation either in the reference itself, or within the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) a reasonable expectation of success, and (3) a teaching or suggestion in the prior art reference of all of the claim limitations (MPEP § 2143). *In re Vacek*, 947 F. 2d. 488 (Fed. Cir. 1991). The combination fails on all counts.

First the combination fails to teach each limitation of the present invention. Odle discloses the use of medium-chain triglycerides by neonatal piglets where the chain length of even- and odd-carbon fatty acids and apparent digestion/absorption and hepatic metabolism. However, there is nothing in Odle that enables or teaches a method of suppressing the effects of translocase deficiency of a prematurely-born human infant by identifying an infant suspected of having a translocase deficiency; and administering to an infant suspected of having a translocase deficiency a composition comprising a seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives thereof. First, there is NOTHING in Odle that relates to the treatment of humans having a translocase deficiency. Second, there is nothing in Odle that indicates that a seven-carbon fatty acid is safe for consumption by humans or has any particular nutritional benefit to humans.

The addition of Ajinomoto does not cure this deficiency. Specifically, Ajinomoto arguably discloses (but fails to enable) a food composition having triheptanoin or trinonanoin may be prepared by a known synthetic or semi-synthetic method or triglyceride formation from heptanoic acid or nonanoic acid. However, the abstract provides no further disclosure to enable the preparation. At the very most Ajinomoto may disclose a food having triheptanoin. Ajinomoto states that the additives are **not necessarily pure** e.g. **may contain a small amount of fatty acids**. The food stuff used may include proteins (e.g. milk casein, soybean protein), oils (e.g. soybean oil, sunflower oil, corn oil), carbohydrates (e.g. glucose, fructose, maltose, sucrose, dextrin, corn starch, xylitol, sorbitol), vitamins and minerals. The compsns. do not produce excess ketones aggregating the condition of diabetes. They are readily absorbed from the digestive organ to supply calorie source without participation of insulin, prevent disintegration of body protein, decreases the blood sugar level, decrease the urinary sugar, and improve the condition of diabetes. In addition, Ajinomoto fails to enable anything as it fails to teach the used how to make and use the subject matter of that is disclosed. Ajinomoto fails to teach a composition stating that the food may have triheptanoin or trinonanoin and that it is not necessarily pure e.g. may contain a small amount of fatty acids.

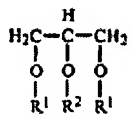
The further addition of Jandacek does not cure these deficiencies. The combination still does not teach a method of suppressing the effects of translocase deficiency of a prematurely-

born human infant by identifying an infant suspected of having a translocase deficiency; and administering to an infant suspected of having a translocase deficiency a composition comprising a seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives thereof. Jandacek may disclose a nutritional fat suitable for enteral and parenteral products. Although glycerol esterified to various compositions are disclosed in Jandacek a triheptanoin composition is not. Jandacek does not disclose identifying an infant suspected of having a translocase deficiency nor does Jandacek disclose the administering to an infant suspected of having a translocase deficiency a composition comprising a seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives thereof. In fact, Jandacek does not relate to translocase deficiency of a prematurely-born human infant in any way. Even if Jandacek did disclose an odd carbon fatty acid of seven or less carbons (which it does not), it would not anticipate the present invention because Jandacek does not enable one skilled in the art to practice the claimed invention, and does not place the allegedly disclosed matter in the possession of the public.

> Further, to anticipate a claim, "a reference must disclose every element of the challenged claim and **enable one skilled in the art to make the anticipating subject matter**." PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1566, 37 U.S.P.Q.2d 1618, 1624 (Fed. Cir. 1996). As stated by the Courts in Akzo N.V. v. ITC, 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986) and Titanium Metals Corp. v. Banner, 227 U.S.P.Q. 773, 778 (Fed. Cir. 1985), the anticipating prior art reference "**must enable one skilled in the art to practice the claimed invention**, thus placing the allegedly disclosed matter in the possession of the public." (emphasis added)

The mere broad listing of different compounds by Jandacek does not place a seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives thereof in possession of the public. Jandacek provides nothing more than a laundry list of possible triglyceride compounds. Jandacek discloses a list of R groups that are a part of the triglyceride that includes n-heptanoyl, n-octanoyl, n-nonanoyl, n-decanoyl, and n-undecanoyl, lauroyl, myristoyl, palmitoyl, stearoyl, oleoyl, linoleoyl, linolenyl groups; however, no indication as to which R groups may be used with another R group and which combinations may be used. Jandacek merely teaches a laundry list of compounds that can be present at the particular R group but provides no indication of which R group combinations are operable.

The present application relates to nutritional fats particularly suitable for enteral and parenteral products. These fats consist essentially of from about 50 to 100% by weight triglycerides of the following formula:



wherein each R^1 group is selected from n-heptanoyl, n-octanoyl, n-nonanoyl, n-decanoyl, and n-undecanoyl groups; and the R^2 groups comprise from 0 to about 90% saturated acyl groups selected from n-heptanoyl, n-octanoyl, n-nonanoyl, n-decanoyl, n-undecanoyl, lauroyl, myristoyl, palmitoyl, stearoyl and mixtures thereof; from 0 to about 90% oleoyl groups; from about 10 to 100% linoleoyl groups; and from 0 to about 10% linolenoyl groups.

Jandacek is not enabling and its mere broad listing of possible different compounds does not place seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives thereof in possession of the public. See additionally, *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 586 F. Supp. 1176, 1221, 222 USPQ 863 (D. Kan. 1984). af'd in part & rev'd in pan, 772 F.2d 1570, 227 USPQ 177 (Fed. Cir. 1985) ("**a printed publication which merely names a new compound or substance is insufficient as an anticipation.**") (emphasis added); *Air Products & Chem.. Inc. v. Chas. S. Tanner Co.*, 219 USPQ 223 (D. S.C. 1983) ("a prior art reference which contains a **broad general disclosure requiring guessing, testing, speculation or 'picking and choosing' from an encyclopedic disclosure will not anticipate.**") (emphasis added). The only examples, presented by Jandacek are triglyceride with 3 even numbered carbon chains attached. Specifically, an 18 carbon chain and two 8 carbon chains attached to a glycerol, see Column 4, lines 12-13 of Jandacek below:

The synthesis of 2-linoleoyl-1,3-dioctanoin according to the present invention is described as follows:

The examples in Jandacek are triglyceride, i.e., glycerol that is esterified with three <u>even</u> chain fatty acids, i.e., a 18 carbon chain and 2 8 carbon chains, see above. Jandacek doesn't even teach/enable a triglyceride with an odd carbon fatty acid of seven or less carbons.

Furthermore, Jandacek does not enable heptanoates, heptanoyl or how to make and use any odd carbon chain fatty acids. Jandacek does not disclose a source for odd chain fatty acids

(e.g., n-heptanoyl), although other sources are discussed, e.g., "Particularly preferred vegetable oils for forming these fatty acid mixtures include soybean oil, corn oil, sunflower oil, safflower oil, and mixtures thereof" Column 4, lines 3-6 of Jandacek. Jandacek provides no guidance to making seven carbon fatty acid compositions selected from triheptanoin or n-heptanoic acid or derivatives thereof, how to purify a seven carbon fatty acid compositions selected from triheptanoin or n-heptanoic acid or derivatives thereof, how much of the seven carbon fatty acid compositions to administer to an infant or any other specific teaching the a seven carbon fatty acid compositions selected from triheptanoin or n-heptanoic acid or derivatives thereof. Jandacek does not disclose how to isolate, purify, characterize or identify the odd chain fatty acids (e.g., n-heptanoyl). In addition, Jandacek provides no guidance to how to identify an infant suspected of having a translocase deficiency nor does Jandacek provide any guidance on how to administer the composition to an infant or how much to administer to an infant suspected of having a translocase deficiency. The mere mention of the term "n-heptanoyl" does not provide the skilled artisan the ability to obtain, make or use an odd carbon chain fatty acid without a specific teaching. The law is clear that there can be no anticipation if there is no enablement in the art cited. *Eibel Process Co. v Minnesota & Ontario Paper*, 261 U.S. 45, 60 (1923).

As a result, the deficiencies in the Odle is not cured by the addition of Ajinomoto and Jandacek. The combination fails to disclose a method of suppressing the effects of translocase deficiency of a prematurely-born human infant by identifying an infant suspected of having a translocase deficiency and administering to an infant suspected of having a translocase deficiency a composition comprising a seven carbon fatty. Individually the references fail to teach the present invention and the combination still fails to teach the instant invention.

Second, the combination fails to provide a suggestion to modify the reference and fails to provide a reasonable expectation of success.

Accordingly, Applicants respectfully submit that claims are not obvious over the combination of Odle and Ajinomoto and Jandacek. and are, therefore, allowable under 35 U.S.C. § 103(a). Applicants respectfully request that the rejection of claim be withdrawn.

CONCLUSION

In light of the foregoing, Applicant submits that claims 15-17 and 21-36 are in condition for allowance, and an early Notice of Allowance of all pending claims is respectfully solicited. The Examiner is invited to call the undersigned at the below-listed telephone number if a telephone conference would expedite or aid the prosecution and examination of this application.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: October 29, 2008.

Respectfully submitted,

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